IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

CAROL SUE CAMPBELL, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-08633

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Defendant's Renewed Motion for Judgment as a Matter of Law & Motion for New Trials*)

Pending before the court are defendant Boston Scientific Corporation's Renewed Motion for Judgment as a Matter of Law [Docket 581] and Motion for New Trials [Docket 579]. For the reasons discussed below, the defendant's motions are **DENIED**.

I. Background

This case consolidated the cases of four plaintiffs within the Boston Scientific Corporation ("BSC") MDL, MDL 2326. (Pretrial Order # 78 [Docket 9]).[1] At present, the BSC MDL contains approximately 19,000 individual cases. The Judicial Panel on Multidistrict Litigation assigned the BSC MDL to this court, along with six other MDLs that concern the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). More than 70,000 cases are currently pending in the MDLs. In this particular case, the plaintiffs allege injuries

[1] Although the claims of all four plaintiffs resulted in jury verdicts, on September 29, 2016, the court entered an order dismissing one of the three plaintiffs, Jacquelyn Tyree, because the parties advised of a pending settlement of Ms. Tyree's claims. [ECF No. 610.]

associated with implantation of the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx"), a polypropylene mesh product manufactured by BSC to treat SUI.[2]

A. Wilson

Dr. Bhanot performed Chris Wilson's implant surgery on May 20, 2010. (Short Form Compl., No. 2:14-cv-5475 [Docket 1], at 3). Approximately ten to twelve months after her surgery, Ms. Wilson began to experience pain in her abdomen, vagina, and pelvis, which prompted her to visit the emergency room. (Trial Tr. (Nov. 5, 2014) [Docket 485], at 809:1–10). Ms. Wilson eventually visited a gynecologist who diagnosed her with bilateral cysts in her ovaries and fibroids in her uterus. (*Id.* at 809:11–19). Dr. Jagganath, Ms. Wilson's general practitioner, prescribed pain pills, which only provided temporary relief. (*Id.* at 809:20–24, 810:10–18). Dr. Jagganath suggested Ms. Wilson follow up with her urologist, Dr. Bhanot, who recommended Ms. Wilson undergo a second surgery. (*Id.* at 811:5–8, 813:21–24). After the second surgery, Ms. Wilson continued to experience pain in her pelvis and vagina. (*Id.* at 815:1–9). Dr. Bhanot suggested Ms. Wilson return to Dr. Jagganath, who referred her to a back and spine specialist. (*Id.* at 815:14–19). After finding no medical issues associated with her back and spine, Ms. Wilson returned again to Dr. Jagganath and, subsequently, to Dr. Bhanot. (*Id.* at 816:2–5, 816:18). Dr. Bhanot recommended Ms. Wilson have a colonoscopy; however, both Ms. Wilson and Dr. Jagganath did not believe it was necessary. (*Id.* at 817:8–16). Attributing her injuries to the Obtryx, Ms. Wilson filed suit against BSC on January 29, 2014. (Short Form Compl., No. 2:14-cv-5475 [Docket 1]).

[2] The facts relayed in this section, though primarily pulled from the trial testimony, are not intended to be exhaustive lists of the evidence presented at trial and instead provide a brief background on each plaintiff's medical history as it relates to the Obtryx.

B. Campbell

Dr. Bhanot performed Carol Campbell's implant surgery on January 6, 2011. (Short Form Compl., No. 2:13-cv-18786 [Docket 1], at 3). Approximately ten weeks after her surgery, Ms. Campbell attempted to have intercourse with her boyfriend, but they both experienced pain, prompting her to return to Dr. Bhanot. (Trial Tr. (Nov. 10, 2014) [Docket 487], at 1053:14–20). Because Ms. Campbell's mesh had eroded, Dr. Bhanot recommended she undergo a revision surgery, which took place on April 7, 2011. (*Id.* at 1054:17–21, 1055:14–15, 1056:11–14). After her revision surgery, Ms. Campbell continued to experience dyspareunia and returned to see Dr. Bhanot. (*Id.* at 1057:3–12). Eventually, Ms. Campbell sought a second opinion and visited Dr. Kasturi in October 2011. (*Id.* at 1057:21–22, 1058:5–10). During the October visit, Dr. Kasturi removed a piece of mesh from inside Ms. Campbell. (*Id.* at 1058:20–1059:3). The following month, Dr. Kasturi removed additional mesh. (*Id.* at 1059:15–24). Ms. Campbell's SUI returned, and she received a bulking injection, performed by Dr. Lohri, in an attempt to treat her symptoms. (*Id.* at 1060:10–12, 1061:2–14). However, her relief was only temporary and she continues to suffer pelvic pain. (*Id.* at 1063:22–23). Attributing these injuries to the Obtryx, Ms. Campbell filed suit against BSC on July 10, 2013. (Short Form Compl., No. 2:13-cv-18786 [Docket 1]).

C. Blankenship

Dr. Lassere performed Jeanie Blankenship's implant surgery on April 8, 2009. (Short Form Compl., No. 2:13-cv-22906 [Docket 1], at 4). Approximately nine weeks after her surgery, Ms. Blankenship experienced dyspareunia. (Trial Tr. (Nov. 12, 2014) [Docket 501], at 1138:18–20). For the next couple of weeks, Ms. Blankenship also had trouble voiding her bladder and suffered painful urination. (*Id.* at 1139:18–1140:13). Eventually, Ms. Blankenship returned to see Dr. Lassere. (*Id.* at 1143:13–17). In July 2012, Ms. Blankenship underwent a revision surgery. (*Id.* at

1144:4–6). Following her second surgery, Ms. Blankenship's SUI returned, and she continued to experience pelvic pain. (*Id.* at 1147:19–21, 1148:10–11). In March 2013, Dr. Capelle performed a third surgery on Ms. Blankenship to implant a new product. (*Id.* at 1149:21–22, 1150:7–9). The new implant successfully treated Ms. Blankenship's SUI; however, she continues to experience both pelvic pain and dyspareunia. (*Id.* at 1152:4–7, 1152:21–1153:19). Attributing these injuries to the Obtryx, Ms. Blankenship filed suit against BSC on September 12, 2013. (Short Form Compl., No. 2:13-cv-18786 [Docket 1]).

D. Trial

Trial began on October 31, 2014, before the Honorable Irene C. Berger, United States District Judge for the Southern District of West Virginia.[3] After eleven days of trial, the plaintiffs ultimately presented four claims to the jury: strict liability for defective design; strict liability for failure to warn; negligence; and punitive damages. (Verdict Form for Jeanie Blankenship [Docket 522]; Verdict Form for Carol Campbell [Docket 530]; Verdict Form for Chris Wilson [Docket 534]).[4] The jury returned a verdict in favor of the plaintiffs on all claims. In so doing, the jury awarded the following damages:

- Wilson - $3,750,000 in compensatory damages and $1,000,000 in punitive damages (Verdict Form for Chris Wilson [Dockets 534, 536]).
- Campbell - $3,250,000 in compensatory damages and $1,000,000 in punitive damages (Verdict Form for Carol Campbell [Dockets 530, 532]).

[3] Judge Berger conducted this consolidated trial while I simultaneously conducted a consolidated BSC trial in the Southern District of Florida. Subsequently, the case was transferred back to me. [Docket 576].

[4] The court dismissed the plaintiffs' other claims upon motions for summary judgment. (*See*; Mem. Op. & Order re: Mot. for Summ. J. re: Blankenship [Docket 449]; Am. Mem. Op. & Order re: Mot. for Summ. J. re: Campbell [Docket 453]; Am. Mem. Op. & Order re: Mot. for Summ. J. re: Wilson [Docket 454]).

- Blankenship - $4,250,000 in compensatory damages and $1,000,000 in punitive damages (Verdict Form for Jeanie Blankenship [Dockets 522, 524]).

At the conclusion of the plaintiffs' case, BSC orally moved for judgment as a matter of law on each claim pursuant to Rule 50(a) of the Federal Rules of Civil Procedure. (Trial Tr. (Nov. 12, 2014) [Docket 501], at 1210:12–14). Judge Berger granted the motion in part with respect to the issues of economic damages and breach of warranty and denied the motion with respect to negligence, strict liability, and punitive damages. (Trial Tr. (Nov. 17, 2014) [Docket 504], at 1959:16–1960:9). Then, at the close of its case, BSC renewed its Rule 50(a) motion for judgment as a matter of law on the remaining claims, and Judge Berger reaffirmed her earlier ruling and denied the motion. (Trial Tr. (Nov. 18, 2014) [Docket 541], at 2202:15–18, 2205:15–25). I now consider BSC's Renewed Motion for Judgment as a Matter of Law ("BSC's Renewed Motion") [Docket 581] pursuant to Rule 50(b), along with its Motion for New Trials [Docket 579] under Rule 59.

II. Renewed Motion for Judgment as a Matter of Law

A. Legal Standard

Pursuant to Federal Rule of Civil Procedure 50(a), a court may grant judgment as a matter of law "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). When considering a party's motion for judgment as a matter of law, the court must "view the evidence in the light most favorable" to the non-moving party and "draw all reasonable inferences in his favor without weighing the evidence or assessing the witnesses' credibility." *Baynard v. Malone*, 268 F.3d 228, 234–35 (4th Cir. 2001). Judgment as a matter of law is inappropriate if a reasonable jury could find in favor of the non-moving party. *Id.* at 235.

On the other hand, a court may grant judgment as a matter of law if the "evidence presented supports only one reasonable conclusion as to the verdict." *Bank of Montreal v. Signet Bank*, 193 F.3d 818, 831 (4th Cir. 1999).

Rule 50 also states that "[i]f the court does not grant a motion for judgment as a matter of law made under Rule 50(a), the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed. R. Civ. P. 50(b). After the matter is submitted to the jury, the Rules allow a movant to file a renewed motion for judgment as a matter of law. *Id.* "When a jury verdict has been returned, judgment as a matter of law may be granted only if, viewing the evidence in a light most favorable to the non-moving party (and in support of the jury's verdict) and drawing every legitimate inference in that party's favor, the only conclusion a reasonable jury could have reached is one in favor of the moving party." *Int'l Ground Transp. v. Mayor & City Council of Ocean City, Md.*, 475 F.3d 214, 218–19 (4th Cir. 2007).

While courts should not simply rubber stamp a jury's verdict, judgment as a matter of law is a remedy to be applied sparingly and only in the most extraordinary circumstances. 9B Charles Wright & Arthur Miller, *Federal Practice and Procedure* § 2524 (3d ed. 2008); *see also, e.g.*, *Sawyer v. Asbury*, 861 F. Supp. 2d 737, 743–44 (S.D. W. Va. 2012) (submitting case to jury despite "deep concerns," but granting post-verdict motion for judgment as a matter of law where video evidence contradicted trial testimony), *aff'd*, 537 F.App'x 283 (4th Cir. 2013). Put simply, a court "may not disturb the [jury] verdict where there was sufficient evidence for a reasonable jury to find in the non-movant's favor." *Dotson v. Pfizer, Inc.*, 558 F.3d 284, 292 (4th Cir. 2009).

B. Discussion

I decline to disturb the jury's verdict in this case because, as explained below, there was more than sufficient evidence from which a reasonable jury could find in favor of the plaintiffs on each of their claims.[5]

1. Strict Liability—Design Defect

In West Virginia, "the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is *not reasonably safe for its intended use*." Syl. pt. 4, *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666 (W. Va. 1979) (emphasis added). The court in *Morningstar* explains that the standard of reasonable safeness is judged by what a reasonably prudent manufacturer would have done and states:

> The term "unsafe" imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

Syl. pt. 5, 253 S.E.2d at 667. This standard is West Virginia's version of the risk-utility analysis employed by several other states, in which design defect is determined by balancing the product's risk of harm against the cost of reducing that risk. *Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 812 n.1 (S.D. W. Va. 2015), *available at* 2015 WL 4635573; (*see also* Trial Tr. (Nov. 19, 2014) [Docket 542], at 2244:13–16 ("In determining whether you believe the Obtryx is or is not reasonably safe for its intended use, you may consider the utility of the design against potential risks of harm created.")).

[5] The court will not discuss any issues not specifically raised or preserved below.

a. Not Reasonably Safe

BSC first argues that the plaintiffs failed to establish that the Obtryx is "not reasonably safe" because it is within the standard of care for the treatment of SUI. BSC conflates the standard for medical malpractice with that used for strict liability. *See S K Hand Tool Corp. v. Lowman*, 479 S.E.2d 103, 106 (Ga. Ct. App. 1996) ("A claim of strict liability is not proved by reference to 'a reasonable degree of skill and care' as measured against a certain community; the nature of a strict liability claim is not that *services* were negligently provided."). Here, the question is whether the *manufacturer* used reasonable care in designing the Obtryx. *See Church v. Wesson*, 385 S.E.2d 393, 396 (W. Va. 1989). Industry custom—i.e., the standard of care in the medical community—is but one factor the jury could have considered as part of its risk-utility analysis. *See Estep v. Mike Ferrell Ford Lincoln-Mercury, Inc.*, 672 S.E.2d 345, 356–57 (W. Va. 2008) (explaining that a jury may consider compliance with federal safety standards, but that such compliance is not conclusive proof of a reasonable design); *see also Johnson v. General Motors Corp.*, 438 S.E.2d 28, 39 (W. Va. 1993) ("I charge you that industry standards are not conclusive as to ordinary care and design or manufacture, but rather are admissible evidence for your consideration, together with all the other evidence in this case."). Furthermore, although "[c]ourts will not lightly presume an entire industry negligent," *In re City of New York*, 522 F.3d 279, 285 (2d Cir. 2008), "a whole calling may have unduly lagged in the adoption of new and available devices. . . . [T]here are precautions so imperative that even their universal disregard will not excuse their omission." *The T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932).

Accordingly, despite expert testimony indicating that use of the Obtryx is within the standard of care in the medical community, a reasonable jury could balance the risks and benefits based on the significant evidence the plaintiffs produced at trial on the Obtryx's risks. For example,

Dr. Rosenzweig testified that the Obtryx is difficult to remove from a woman's body because the mesh degrades, gets hard and brittle, and cracks. (Trial Tr. (Nov. 4, 2014) [Docket 484], at 428:13–18, 429:7–8). Dr. Rosenzweig also described the way in which the mesh shrinks and contracts, causing a chronic foreign body reaction, scarring, and inflammation. (*See id.* at 429:17–24, 430:10–22, 431:12–17). Because of the different processes the mesh undergoes in a woman's body, Dr. Rosenzweig concluded that a polypropylene mesh mid-urethral sling implanted using the transobturator approach—like the Obtryx—is a "bad idea" and that safer alternatives exist with fewer complications. (*Id.* at 482:4–12). Similarly, Dr. Mays testified that it is well-established and generally known in the scientific community that polypropylene degrades and will break down in the human body when exposed to strong oxidizing agents, like peroxide. (Trial Tr. (Nov. 5, 2014) [Docket 485], at 625:8–12, 632:10–19 (likewise concluding that using Marlex for permanent implantation in the human body is not a "good idea")).

Dr. Walker focused more specifically on contraction and shrinkage at trial, explaining how the breakdown of the Obtryx mesh results in inflammation and "[a] tremendous amount of pain." (Trial Tr. (Nov. 10, 2014) [Docket 487], at 873:3–17 (discussing periurethral banding as the result of shrinkage, which creates a "banjo-like effect")). Lastly, Dr. Margolis testified that, while it is "extraordinarily easy to put in a sling," it is quite difficult to remove polypropylene mesh from a woman's vagina because the sling undergoes major changes, including shrinkage, contracture, and scarification. (Margolis Dep. Tr. [Docket 570-7], at 35:20–39:3).[6] Dr. Margolis also described the way in which mesh "will roll up like a rope or banjo string, or tighten up," causing nerve entrapment and therefore, pain. (*Id.* at 39:3–4, 95:18–96:5, 96:14–15 (using banding and contracting interchangeably and explaining that "banding by definition includes shrinkage")).

[6] Video of Dr. Margolis's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Nov. 12, 2014) [Docket 501], at 1125:19–20).

From this evidence, a reasonable jury could conclude that the risks associated with the Obtryx are not justified by its benefits and, as a result, the product is not reasonably safe.

b. Specific Design Flaw & Proximate Causation

BSC also argues that the plaintiffs' claims for design defect fail because they did not present evidence of a specific design flaw in the Obtryx or link that flaw to any individual plaintiff's injuries. To begin, the law in West Virginia, on which the jury was properly instructed, does not require evidence of a specific design flaw to succeed on a claim for strict liability. Syl. pt. 3, *Anderson v. Chrysler Corp.*, 403 S.E.2d 189 (W. Va. 1991) ("Circumstantial evidence may be sufficient to make a prima facie case in a strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect. Moreover, the plaintiff must show there was neither abnormal use of the product nor a reasonable secondary cause for the malfunction.").[7] Regardless, a reasonable jury could conclude that the Obtryx is not reasonably safe based on evidence of the specific defects discussed above (e.g. difficulty of removal; contraction, shrinkage, and banding; degradation; scarring). Because I **FIND** that the plaintiffs' experts specifically connected at least one of the above defects to each plaintiff's injuries, a reasonable jury would have no need to "infer the existence of a defect by circumstantial evidence." *Bennett v. Asco Services, Inc.*, 621 S.E.2d 710, 717 (W. Va. 2005). I will briefly review the causation evidence for each plaintiff that supports my finding.

i. Wilson

[7] At trial, Judge Berger provided the following instruction: "A plaintiff is not required to establish a strict products liability cause of action by identifying a specific defect that caused the loss, but instead may permit a jury to infer the existence of a defect by circumstantial evidence." (Trial Tr. (Nov. 19, 2014) [Docket 542], at 2244:2–9).

After reviewing Ms. Wilson's medical records and performing a physical examination, (Trial Tr. (Nov. 10, 2014) [Docket 487], at 880:5–8), Dr. Walker concluded that the Obtryx mesh implanted in Ms. Wilson caused her permanent problems. (*Id.* at 894:12–22 (noting banding, mesh erosion, and nerve pain)). Specifically, Dr. Walker discovered chronic inflammation as a result of the mesh shrinking, contracting, and tightening. (*Id.* at 881:2–5, 881:22–882:2). Dr. Walker also testified that Ms. Wilson suffers from periurethral banding, which "is a source of pain." (*Id.* at 882:3–13). Furthermore, Dr. Walker performed a differential diagnosis in which he ruled out other potential causes of Ms. Wilson's pain, including cystocele, fibroids, and ovarian cysts. (*See id.* at 890:3–891:24).

ii. Campbell

Dr. Margolis also testified as to specific causation for Ms. Campbell on her claim of strict liability for design defect. After reviewing Ms. Campbell's medical history and performing a physical examination, (Margolis Dep. Tr. [Docket 570-7], at 131:9–15), Dr. Margolis concluded that the Obtryx caused Ms. Campbell's dyspareunia and chronic pelvic pain. (*Id.* at 144:11–17). Specifically, Dr. Margolis discovered palpable mesh and substantial scar tissue in Ms. Campbell's anterior vaginal wall. (*Id.* at 134:17–135:21). Dr. Margolis later explained that mesh erosions, like those experienced by Ms. Campbell, repeatedly cause inflammation, scarring, and pain. (*Id.* at 162:3–9). Furthermore, Dr. Margolis ruled out Ms. Campbell's past gynecological issues through differential diagnosis and ultimately concluded that the Obtryx is the cause of her permanent injuries. (*Id.* at 145:14–24, 165:8–21)

iii. Blankenship

After reviewing Ms. Blankenship's medical records, deposition testimony, and treating physicians' deposition testimony, Dr. Rosenzweig concluded that Ms. Blankenship would have

ongoing problems as a result of the Obtryx mesh remaining inside her body. (Trial Tr. (Nov. 4, 2014) [Docket 484], at 391:10–13, 473:5–18). Specifically, Dr. Rosenzweig discussed how difficult it is to remove the mesh because of its location in the muscle: "The mesh is going through a muscle. And that, that becomes a fulcrum of pain that spreads out through the muscle and will cause the pelvic floor muscles to spasm. And that's been described in Jeanie Blankenship currently, that she's got spasm of her pelvic floor muscles." (*Id.* at 437:3–8). He also testified that while the mesh remains inside her body, it will continue to degrade, contract, cause a chronic foreign body reaction, and cause chronic inflammation, all of which lead to discomfort. (*Id.* at 438:4–9, 473:5–18). Ultimately, Dr. Rosenzweig "did not see anything that would lead to irritation of the muscle that would lead to pelvic floor muscle spasm except mesh, a foreign body, in the muscles of the pelvic floor." (*Id.* at 474:15–18).

Because each plaintiff presented sufficient causation evidence, BSC's Renewed Motion [Docket 581] on the plaintiffs' claim of strict liability for design defect is **DENIED**.

2. Negligence

As an initial matter, BSC contends that there is a "conceptual overlap between negligence and strict products liability claims in West Virginia;" therefore, "if each Plaintiff's strict liability claims fail, so do her claims for negligence." (BSC's Mem. of Law in Supp. of Its Renewed Mot. ("BSC's Mem.") [Docket 582], at 16). The law in West Virginia is clear in that product liability actions premised on strict liability and negligence are "theor[ies] contain[ing] different elements which plaintiffs must prove in order to recover." Syl. pt. 6, *Ilosky*, 307 S.E.2d at 603. Moreover, even assuming there is overlap between the plaintiffs' strict liability and negligence claims, I **FIND** that the plaintiffs presented sufficient evidence to *succeed* on their strict liability claims. Therefore, BSC's argument is without merit.

In West Virginia, a plaintiff must establish four basic elements to succeed on a claim for negligence: (1) duty; (2) breach of duty; (3) causation; and (4) damages. *Price v. LaMaster*, No. 14-0678, 2015 WL 1128671, at *3 (W. Va. 2015); *see also Strahin v. Cleavenger*, 603 S.E.2d 197, 205 (W. Va. 2004) ("To prevail in a negligence suit, the plaintiff must prove by a preponderance of the evidence that the defendant owed a legal duty to the plaintiff and that by breaching that duty the defendant proximately caused the injuries of the plaintiff."). Here, the plaintiffs' negligence claims fall into the same two categories as their strict liability claims: (1) negligent design and (2) negligent failure to warn.

BSC contends that it used reasonable care in the design and labeling of the Obtryx because it followed industry standards, which did not require BSC to conduct clinical trials. However, as mentioned above, compliance with industry standards is not necessarily proof of reasonable conduct. *See Estep*, 672 S.E.2d at 356–57. Furthermore, Dr. Peggy Pence, testifying on behalf of the plaintiffs, stated that BSC "failed in its responsibilities as the manufacturer of the Obtryx sling to perform the appropriate testing for marketing of the Obtryx sling." (Trial Tr. (Nov. 3, 2014) [Docket 483], at 278:19–22). Dr. Pence also explained how BSC was "on notice [through its experience with the ProteGen sling] . . . that by not doing clinical testing before marketing a product . . . serious safety issues can arise." (*Id.* at 283:24–284:9). Without conducting clinical testing, Dr. Pence testified, BSC had no way of verifying that the Obtryx was safe for permanent implantation in the human body. (*See id.* at 282:2–5). This evidence supports a verdict by a reasonable jury that BSC breached its duty to the plaintiffs in designing the Obtryx.

"The proximate cause of an injury is the last negligent act contributing to the injury and without which the injury would not have occurred." Syl. pt. 1, *Mays v. Chang*, 579 S.E.2d 561 (W. Va. 2003) (citation omitted). With regard to negligent failure to warn, Dr. Pence explained that the

Material Safety Data Sheet ("MSDS") issued by Chevron Phillips Chemical Company LP shows "that there has been no testing to determine [polypropylene's] appropriateness or its fitness for permanent implantation." (Trial Tr. (Nov. 3, 2014) [Docket 483], at 302:11–16). And as discussed further below, Dr. Bhanot testified that had he known about the risks associated with permanent implantation, he would not have used the Obtryx. (Bhanot Dep. Tr. [Docket 570-5], at 238:9–240:10).[8] Dr. Lassere had concerns about the lack of warnings with regard to shrinkage rates, (Lassere Dep. Tr. [Docket 570-6], at 108:23-109:4),[9] which could have been revealed through clinical testing. (*See* Trial Tr. (Nov. 3, 2014) [Docket 483], at 304:10–17 (discussing safety risks that can arise once a product is used in humans)). The design defects discussed above, which were specifically linked to the plaintiffs' injuries through expert testimony, likewise could have been revealed through clinical testing of the Obtryx. Therefore, a reasonable jury could find that BSC's failure to conduct clinical trials before marketing the Obtryx proximately caused the plaintiffs' injuries.

Accordingly, BSC's Renewed Motion [Docket 581] on the plaintiffs' negligence claims is **DENIED**.

3. Strict Liability—Failure to Warn

A claim of strict liability for failure to warn operates under the same standard—not reasonably safe for its intended use—discussed above with regard to the plaintiffs' design defect claims. *See Morningstar*, 253 S.E.2d at 682 ("[A] defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions or

[8] Video of Dr. Bhanot's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Nov. 10, 2014) [Docket 487], at 1044:25–1045:1).

[9] Video of Dr. Lassere's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Nov. 10, 2014) [Docket 487], at 1045:19–20).

labels."). "Use defectiveness covers situations when a product may be safe as designed and manufactured, but which becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner." *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 609 (W. Va. 1983). To recover in a strict product liability action under a theory of failure to warn, the plaintiff must prove that (1) the use of the product was foreseeable; (2) the product was defective due to a failure to warn; and (3) the failure to warn proximately caused the injury. *Addair v. Island Creek Coal Co.*, No. 12-0708, 2013 WL 1687833, at *3 (W. Va. Apr. 17, 2013). Furthermore, having previously concluded that the learned intermediary doctrine would apply in West Virginia in the context of this case, BSC only had a duty to warn the plaintiffs' treating physicians of the risks associated with the Obtryx. *See Tyree v. Boston Scientific Corp.*, 56 F. Supp. 3d 826 (S.D. W. Va. 2014).

a. Adequacy of Warnings

BSC first argues that the plaintiffs failed to meet their burden because "none of Plaintiffs' experts opine that [BSC's] warnings for the Obtryx device were inadequate." (BSC's Mem. [Docket 582], at 3). The lack of this particular expert testimony however, is not fatal to the plaintiffs' failure to warn claims. Product defect arising from failure to warn "is to be tested by what a reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to the economic costs, at the time the product was made." *Morningstar*, 253 S.E.2d at 682–83. Determining the adequacy of a defendant's warnings is a question for the jury. *See Ilosky*, 307 S.E.2d at 611; *see also Eskridge v. Pacific Cycle, Inc.*, 556 F. App'x 182, 190 (4th Cir. 2014) (unpublished) ("The adequacy of the method chosen by the manufacturer to warn the user of a particular danger is generally a question for the jury."). Although the court in

Morningstar discusses an expert witness's role in "evaluating" and "explaining" the adequacy of a product's warnings, it does not explicitly require an expert witness to make this determination. *See Morningstar*, 253 S.E.2d at 682 (noting that the expert witness is *ordinarily* the critical witness and analogizing the problem of product defectiveness to "the defective condition of the mind," in that the jury uses their common sense to apply a "generalized standard given content by expert testimony"); *see also Ilosky*, 307 S.E.2d at 617 (stating that experts *may* testify on the adequacy of a warning).

Of particular significance in this case is the Material Safety Data Sheet ("MSDS") issued by Chevron Phillips Chemical Company LP ("Chevron Phillips") with regard to their Marlex polypropylene. The plaintiffs presented evidence at trial that the MSDS included a Medical Application Caution, which stated: "*Do not use [Chevron Phillips] material in medical applications involving permanent implantation in the human body . . . .*" (Smith Dep. Tr. [Docket 570-1], at 29:20–22) (emphasis added).[10] Charles Smith, a BSC employee responsible for research and development, testified that because Chevron Phillips made no warranties concerning the suitability of its polypropylene for permanent implantation in the body, it was BSC's responsibility to perform such testing. (*Id.* at 31:23–32:4, 32:15–33:2; *see also* Trial Tr. (Nov. 3, 2014) [Docket 483], at 302:11–16 (explaining that the medical application caution is important because it means "there has been no testing to determine [polypropylene's] appropriateness or its fitness for permanent implantation")). However, BSC never performed any clinical—meaning inside the human body—testing on the Obtryx. (*See* Trial Tr. (Nov. 3, 2014) [Docket 483], at 291:6). Furthermore, Dr. Mays, an expert in polymers, confirmed that a scientific basis for the Medical Application Caution exists because polypropylene degrades when exposed to oxidizing agents

[10] Video of Mr. Smith's deposition testimony was played for the jury during trial. (*See* Trial Tr. (Nov. 3, 2014) [Docket 483], at 259:18–19).

present in the human body. (Trial Tr. (Nov. 5, 2014) [Docket 485], at 616:10–13, 625:8–12, 632:10–13 (explaining why he does not think using Marlex for permanent implantation in the human body is a "good idea")).

The plaintiffs also presented evidence, through expert testimony by Dr. Rosenzweig, of mesh shrinkage. (*See* Trial Tr. (Nov. 4, 2014) [Docket 484], at 429:17–430:15). Dr. Rosenzweig explained that mesh shrinkage or contraction puts the Obtryx under tension—when it is supposed to be placed "tension-free"—resulting in painful inflammation and making the mesh nearly impossible to remove. (*Id.* at 430:16–24, 431:12–432:9, 434:12–14 (calling mesh shrinkage and contraction a "significant problem")). Dr. Rosenzweig further testified that a surgeon, in order to attempt to keep the Obtryx tension-free, would need to know about the risk of shrinkage, which is not warned of in the Directions for Use ("DFU"). (*Id.* at 443:24–444:6). Despite this information, BSC did not include any warnings in the DFU indicating that (1) polypropylene is not intended for permanent use in the human body; (2) the Obtryx was not subject to clinical testing; and (3) polypropylene undergoes shrinkage. (*See id.* at 679:19–21, 680:5–7, 687:2–8, 692:9–12, 696:1 ("The DFU would not tell all of those details, no.")).

Here, the plaintiffs offered multiple expert witnesses who testified that certain significant risks were not included in the DFU, particularly those related to the MSDS, and Dr. Rosenzweig testified that shrinkage is a risk about which surgeons would need to know. From this evidence, a reasonable jury could conclude that the DFU was inadequate in that it lacked any reference to the above risks.

b. Proximate Cause

BSC also argues that the plaintiffs failed to show that the lack of warnings proximately caused their injuries. Proximate cause is "that cause which in actual sequence, unbroken by any

independent cause, produced the wrong complained of, without which the wrong would not have occurred." *Wilkinson v. Duff*, 575 S.E.2d 335, 341 (W. Va. 2002) (citation omitted); *see also* syl. pt. 5, *Hartley v. Crede*, 82 S.E.2d 672 (W. Va. 1954) ("The proximate cause of an injury is the last negligent act contributing to the injury and without which the injury would not have occurred."). To establish proximate causation under a theory of failure to warn, the plaintiff must prove that a different warning would have avoided her injuries. *See Meade v. Parsley*, No. 2:09-cv-0038, 2010 WL 4909435, at *5 (S.D. W. Va. Nov. 24, 2010) (applying West Virginia law in a pharmaceutical failure to warn case). Therefore, in accordance with the learned intermediary doctrine, the plaintiff has the burden of showing that a different warning would have caused her implanting physician to "change his behavior in a manner which would have avoided [her injury]." *Tracy v. Cottrell*, 524 S.E.2d 879, 890 n.9 (W. Va. 1999).

i. Wilson & Campbell

In his deposition, Dr. Bhanot, Ms. Wilson's and Ms. Campbell's implanting physician, testified that he relied, at least in part, on the information in the DFU. (Bhanot Dep. Tr. [Docket 570-5], at 199:21–200:4). At the time he implanted the Obtryx, Dr. Bhanot had no knowledge of the Medical Application Caution. (*See id.* at 237:15–238:8). In response to two questions regarding the MSDS, Dr. Bhanot testified that, had he known that Marlex polypropylene was not intended for permanent use in the human body, he would not have used the Obtryx. (*See id.* at 238:9–240:10 ("Q: If you had known that the material safety data sheet for the polypropylene used by Boston Scientific in their Obtryx stated do not use this material in medical applications involving permanent implantation in the human body, would you have used the Obtryx? A: No. Q: If you had known the statement I just read to you about the polypropylene mesh, you wouldn't have implanted it in any of these . . . plaintiffs; is that correct? A: Yes.")).

BSC points out that, on cross-examination, Dr. Bhanot testified that he continues to use the Obtryx "when appropriate," (Bhanot Dep. Tr. [Docket 570-15], at 380:4–16), and that he would not rely on a statement from the polypropylene manufacturer in deciding whether or not to use a particular device. (*See id.* at 395:1–396:3; *see also* Trial Tr. (Nov. 12, 2014) [Docket 501], at 1215:1–6 (plaintiffs' counsel admitting that Dr. Bhanot "flip-flopped" but also noting that "there's certainly a fact issue for the jury to find")). Under Rule 50(b), it is not appropriate for the court to weigh the evidence or assess a witness's credibility. *See Baynard*, 268 F.3d at 234–35. Therefore, giving the plaintiffs the "benefit of all inferences," a reasonable jury could take Dr. Bhanot's testimony upon direct examination as sufficient evidence of proximate causation. *Duke v. Uniroyal Inc.*, 928 F.2d 113, 1417 (4th Cir. 1991).

ii. Blankenship

In his deposition, Dr. Lassere, Ms. Blankenship's implanting physician, testified that he relies on the DFU to help educate him about the risks associated with the Obtryx. (Lassere Dep. Tr. [Docket 570-6], at 79:21–81:22). The majority of Dr. Lassere's testimony concerns whether he would have discussed certain risks with Ms. Blankenship had they been warned of in the DFU. (*See id.* at 86:10–90:16 (addressing risks of chronic pelvic pain and rate of occurrence for dyspareunia)). Under the learned intermediary doctrine, as the jury was properly instructed, BSC "had a duty to adequately warn only the physicians who implant the Obtryx. [BSC] did not have a direct duty to warn consumers such as the plaintiffs." (Trial Tr. (Nov. 19, 2014) [Docket 542], at 2245:3–6). Therefore, the fact that Ms. Blankenship may have been unwilling to accept certain risks is irrelevant to establishing proximate causation in this case. However, at the end of his deposition, when asked specifically whether he "would . . . likely have chosen . . . a different product, if [he] had been aware back in 2009 that the shrinkage rate for the Obtryx sling was greater

than 2%," Dr. Lassere answered in the affirmative. (Lassere Dep. [Docket 570-6], at 108:23–109:4 ("A: Likely.")). Based on this statement, a reasonable juror could conclude that a warning related to shrinkage would have avoided Ms. Blankenship's injuries.

Accordingly, BSC's Renewed Motion [Docket 581] on the plaintiffs' claim of strict liability for failure to warn is **DENIED**.

4. Punitive Damages

"In actions of tort, where gross fraud, malice, oppression, or wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others appear, or where legislative enactment authorizes it, the jury may assess exemplary, punitive, or vindictive damages; these terms being synonymous." Syl. pt. 4, *Mayer v. Frobe*, 22 S.E. 58 (W. Va. 1895). BSC contends that the plaintiffs failed to prove BSC acted with malice and "at best, showed that their paid experts' [sic] disagree with the vast majority of the medical and scientific communities." (BSC's Mem. [Docket 582], at 19). I disagree and **FIND** that the plaintiffs presented sufficient evidence from which a reasonable juror could conclude that BSC acted with the requisite intent in its design and labeling of the Obtryx.

First, the plaintiffs presented evidence related to the recall of the ProteGen, a sling manufactured by BSC prior to the development of the Obtryx. (Trial Tr. (Nov. 3, 2014) [Docket 483], at 284:2–3). The ProteGen, which never underwent clinical testing, was recalled because of safety concerns, which Dr. Pence testified put BSC "on notice" as to the importance of clinical testing. (*Id.* at 283:4–9; *see also* Miragliuolo Dep. Tr. [Docket 570-2], at 145:15–146:4 (noting that the rate of vaginal erosion with the ProteGen was higher than BSC's acceptable standard of performance)).[11] As a result of the ProteGen's failure, BSC decided it would gather clinical data

[11] Video of Mr. Miragliuolo's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Nov. 3, 2014) [Docket 483], at 366:3–4).

on future slings in order to adequately assess product performance. (*See* Miragliuolo Dep. Tr. [Docket 570-2], at 146:9–147:2 ("In connection with any future sling materials, Boston Scientific will gather clinical data to assess product performance in a broad spectrum of clinical situations.")). Despite this intention, BSC never performed any clinical testing on the Obtryx.

Furthermore, the Medical Application Caution in the MSDS, warning against the use of Marlex polypropylene for permanent implantation in the human body, was discussed extensively throughout the trial. It plainly stated: "*Do not use [Chevron Phillips] material in medical applications involving permanent implantation in the human body* . . . ." (Smith Dep. Tr. [Docket 570-1], at 29:20–22) (emphasis added). Dr. Pence testified that the Medical Application Caution was significant because it showed that there was no testing done to determine whether it was safe to permanently implant polypropylene in a woman's body. (Trial Tr. (Nov. 3, 2014) [Docket 483], at 302:11–16). Yet even after learning of the MSDS, BSC did not conduct human testing, initiate any further studies, halt release of the Obtryx, or disclose the new information. (*Id.* at 302:17–304:9 ("Q: Okay. Was this the first time that any chemical company was telling Boston Scientific not to use [polypropylene] for permanent implantation, that you're aware of? A: Yes, that's correct. Q: What did they do? A: They did nothing. They kept selling -- well, they marketed the product in August of 2004 without doing any testing to determine the appropriateness of the polypropylene for permanent implantation[.]")). As discussed above, the DFU did not include any warnings with regard to the Medical Application Caution or lack of clinical testing.

Lastly, the plaintiffs presented evidence related to a study conducted by Dr. Hilary Cholhan and funded in part by BSC. The Cholhan study "identified pariurethral banding as a previously unreported complication" of the Obtryx and noted that "[s]urgeons should be aware of the pariurethral banding and subsequent internal dyspareunia as a potential complication." (Trial Tr.

(Nov. 4, 2014) [Docket 484], at 465:20–24). When asked about the study, Alex Robbins, a BSC sales representative and training manager, stated that, because of its negative outcome, the study would not be useful to the sales force and should not be given to physicians. (Robbins Dep. Tr. [Docket 570-3], at 75:24–80:6 ("I certainly wouldn't hand this out to any physicians.")).[12]

In sum, BSC knew that safety issues can arise when a product does not undergo clinical testing, failed to respond to explicit warnings from the manufacturer that polypropylene should never be used permanently in the human body, and suggested hiding negative studies to physicians considering using the Obtryx. Drawing all inferences in the light most favorable to the plaintiffs, I **FIND** that a reasonable jury could use this evidence to conclude that BSC's conduct justified an award of punitive damages.

Accordingly, BSC's Renewed Motion [Docket 581] on the plaintiffs' punitive damages claim is **DENIED**.

III. Motion for New Trials

Having denied BSC's Renewed Motion in its entirety, I now turn to BSC's Motion for New Trials.

A. Legal Standard

Federal Rule of Civil Procedure 59 allows a court to grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). The Fourth Circuit has set forth a three-prong standard to govern Rule 59 motions:

> [I]t is the duty of the judge to set aside the verdict and grant a new trial, if he is of the opinion that (1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict.

[12] Video of Mr. Robbins's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Nov. 4, 2014) [Docket 484], at 599:10–11).

Atlas Food Sys. & Servs., Inc. v. Crane Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996) (internal citations and brackets omitted). When considering a motion for a new trial, the "crucial inquiry," particularly when employing the third prong, is "whether an error occurred in the conduct of the trial that was *so grievous* as to have rendered the trial unfair." *Bristol Steel & Iron Works v. Bethlehem Steel Corp.*, 41 F.3d 182, 186 (4th Cir. 1994) (emphasis added).

The decision to grant or deny a new trial "is within the sound discretion of the trial court." *Cline v. Wal-Mart Stores, Inc.*, 144 F.3d 294, 301 (4th Cir. 1998). Moreover, the discretion bestowed under Rule 59 "should be exercised sparingly." *United States v. Arrington*, 757 F.2d 1484, 1486 (4th Cir. 1985); *see also United States v. Perea*, 458 F.2d 535, 536 (10th Cir. 1972) ("A motion for a new trial is generally not regarded with favor, and is granted only with *great caution*." (emphasis added)). I conclude that BSC has fallen short of clearing the high bar set by Rule 59.

B. Discussion

BSC asserts four grounds for new trials: (1) the verdicts resulting from consolidation will result in a miscarriage of justice; (2) the verdicts are excessive; (3) the verdicts are against the weight of the evidence; and (4) errors at trial caused a miscarriage of justice.[13]

1. Consolidation

Federal Rule of Civil Procedure 42(a) gives district courts broad discretion to consolidate cases involving common questions of law or fact. *See Arnold v. E. Air Lines, Inc.*, 681 F.2d 186, 192 (4th Cir. 1982) ("The decision whether to sever or to consolidate whole actions or sub-units for trial is necessarily committed to trial court discretion."). Yet again, BSC challenges my decision to consolidate and asserts that the verdicts resulting from consolidation reflect a

[13] The court will not discuss any issues not specifically raised or preserved below.

miscarriage of justice.

a. Past Compensatory Damages

With regard to past compensatory damages, BSC argues that the "identical [$250,000] awards show that the jury was unable to distinguish the evidence related to each of the four plaintiffs." At bottom, BSC asks me to infer—in light of the jury's decision to award identical damages—that the jurors experienced confusion at a level constituting a miscarriage of justice. I am not persuaded by this argument.

Most importantly, BSC does not point to any direct source of the jury's alleged confusion (e.g. improper jury instructions). Rather, BSC asks me, in essence, to work backwards—speculating as to what the cause is from the end result. BSC's speculative argument falls well short of demonstrating that "an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair." *Bristol Steel & Iron Works*, 41 F.3d at 186. Furthermore, with regard to future losses, the jury awarded *different* damages, suggesting that the jury understood the instructions provided (i.e., that the plaintiffs' damages may vary plaintiff to plaintiff) and was not otherwise confused. Finally, the cases relied upon by BSC are not directly on point, and I do not find them persuasive in considering whether to order a new trial.[14]

b. Punitive Damages

With regard to punitive damages, BSC contends that the risk of confusion caused by

[14] First, in *Cain v. Armstrong World Indus., Inc.*, the court ordered retrial of part of a consolidated asbestos case for the following reasons: the damages awarded to cancer and non-cancer cases were identical; the jury deliberated for a relatively short time; the damages awards were excessive; and evidence supporting some of the jury's findings was totally lacking. 785 F. Supp. 1448, 1455 (S.D. Ala. 1992). Likewise, in *Agrofollajes, S.A. v. E.I. Du Pont De Nemours & Co.*, the court ordered retrial for each individual plaintiff because the jury was confronted with a "dizzying amount of evidence," including evidence that would not have been admissible had the cases been tried separately, which influenced the jury to award to each plaintiff the same exact percentage of their claimed damages. 48 So. 3d 976, 988 (Fla. Dist. Ct. App. 2010). Although the past compensatory damages here—like the damages considered in *Cain* and *Agrofollajes*—are identical, the other factors guiding the courts' decisions in those cases are not present.

consolidation was unconstitutional. In asserting this argument, BSC relies on the Supreme Court's opinion in *Philip Morris USA v. Williams*, wherein the Court explained: "[T]he Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties or those whom they directly represent, *i.e.*, injury that it inflicts upon those who are, essentially, *strangers to the litigation*." 549 U.S. 346, 353 (2007) (second emphasis added). However, in the instant case, there is no evidence that the jury did not follow the court's instruction to consider each claim separately. (*See* Trial Tr. (Nov. 19, 2014) [Docket 542], at 2233:1–7). Furthermore, contrary to BSC's suggestion, plaintiffs' counsel did not ask the jury to punish BSC for harm caused to other plaintiffs. (*See* Trial Tr. (Nov. 20, 2014) [Docket 543], at 2364:24–2365:4 (referring to BSC's conduct "as it relates to these four ladies"). Therefore, I do not find that the jury's punitive damages "inflict[ed] punishment for harm caused [to] strangers to the litigation." *Philip Morris USA*, 549 U.S. at 357.

BSC next argues that the identical punitive damages awards likewise reveal a due process violation. As noted above, however, such a speculative argument falls well short of demonstrating grievous error. Furthermore, because punitive damages are not compensatory, and instead aim to punish and deter, *see Exxon Shipping Co. v. Baker*, 554 U.S. 471, 504 (2008), the jury's decision to award the same damages is not remarkable where the evidence of BSC's conduct is similar if not identical for each plaintiff. Accordingly, I do not find that the verdicts resulting from the consolidation satisfy the high burden needed to demonstrate a miscarriage of justice.

2. Excessive Verdicts

In West Virginia, a court will not "interfere with jury verdicts claimed to be excessive . . . unless the verdict is monstrous and enormous, at first blush beyond all measure, unreasonable and outrageous, and such as manifestly shows jury passion, partiality, prejudice, or corruption." *Addair*

v. Majestic Petroleum Co., 232 S.E.2d 821, 825 (W. Va. 1977) (citation omitted); *see also Roberts v. Stevens Clinic Hosp., Inc.*, 345 S.E.2d 791, 800 (W. Va. 1986) ("Obviously, applying that standard entails a largely subjective exercise."). Furthermore,

> There is and there can be no fixed basis, table, standard, or mathematical rule which will serve as an accurate index and guide to the establishment of damage awards for personal injuries. And it is equally plain that there is no measure by which the amount of pain and suffering endured by a particular human can be calculated. No market place exists at which such malaise is bought and sold. A person can sell quantities of his blood, but there is no mart where the price of a voluntary subjection of oneself to pain and suffering is or can be fixed.

Crum v. Ward, 122 S.E.2d 18, 23–24 (W. Va. 1961). An award "based upon pain and suffering as adjudged by the jury, that was clearly in their province under the evidence presented" cannot be deemed excessive as a matter of law. *Adkins v. Foster*, 421 S.E.2d 271, 277 (W. Va. 1992).

Here, all three plaintiffs underwent subsequent procedures to repair, revise or remove the mesh, *see supra* Part I, and continue to suffer from what has been diagnosed as permanent pain. (*See* Trial Tr. (Nov. 4, 2014) [Docket 484], at 435:3–7, 435:25–436:4, 438:4–9) (discussing the permanence of Ms. Blankenship's injuries); Trial Tr. (Nov. 10, 2014) [Docket 487], at 894:12–22 (discussing the permanence of Ms. Wilson's injuries); Margolis Dep. Tr. [Docket 570-7], at 109:25–111:14, 171:3–25 (discussing the permanence of Ms. Campbell's injuries, respectively)).

Although BSC contends that the verdicts are excessive because they contemplate the plaintiffs living well into their hundreds, life expectancy is but one factor to consider in reviewing the jury's decision. *See Strahin v. Cleavenger*, 603 S.E.2d 197, 212 (W. Va. 2004) (denying motion for new trial on the ground of an excessive verdict given "Appellee's young age and evidence of the nature and extent of his injury, the continuing pain from the injury and the life expectancy of Appellant"). And I agree with the plaintiffs that "[i]t is not an unreasonable inference that the jury concluded that the monetary value of knowing that the current pain was permanent . . . was higher

on a per year basis than the past pain and suffering." (Pls.' Resp. to BSC's Mot. for New Trials [Docket 600], at 7). Accordingly, BSC has not shown the verdicts are so "monstrous and enormous" that a new trial is warranted. *Addair*, 232 S.E.2d at 825.

3. Against the Weight of the Evidence

When ruling on a motion for a new trial based on the sufficiency of the evidence, the court enjoys "wider" discretion than when ruling on a motion for judgment as a matter of law. *McCracken v. Richmond, F. & P. R. Co.*, 240 F.2d 484, 488 (4th Cir. 1957). In the latter instance, the court must view the evidence in the light most favorable to the non-moving party and resolve any conflict on the non-movant's behalf. If there is substantial evidence in support of the plaintiff's case, the court may not direct a verdict against her, "even though [it] may not believe [her] evidence or may think that the weight of the evidence is on the other side." *Id.* (quoting *Garrison v. United States*, 62 F.2d 41, 42 (4th Cir. 1932)). On a motion for a new trial, however, the court must exercise its "independent judgment after a weighing of all the evidence and any other pertinent factors" and "determin[e] whether the verdict was against the clear weight of the evidence or would result in a miscarriage of justice." *Williams v. Nicols*, 266 F.2d 389, 393 (4th Cir. 1959). In any event, the court may not "reweigh the evidence and set aside the jury verdict merely because the jury could have redrawn different inferences or conclusions or because judges feel that other results are more reasonable." *Lee v. Adrales*, 778 F. Supp. 904, 907 (W.D. Va. 1991) (citation omitted); *see also* 6A J. Moore, *Moore's Federal Practice* ¶ 59.08[5] (stating that the court should "abstain from interfering with the verdict unless it is quite clear that the jury has reached a seriously erroneous result"). Applying this less-stringent standard to the case at bar, I do not believe that BSC has made the required showing to warrant a new trial.

To begin, BSC incorporates its arguments contained in its Memorandum in Support of its

Renewed Motion for Judgment as a Matter of Law [Docket 582]. BSC also contends that the design defect verdicts are against the clear weight of the evidence because the Obtryx is within the standard of care for the treatment of SUI and that the failure to warn verdicts likewise fail for lack of causation. As discussed more fully above, standard of care is but one factor the jury could have considered as part of their risk-utility analysis, and the plaintiffs presented sufficient evidence that the risks associated with the Obtryx are not justified by its benefits. *See supra* Parts 1, 2. With regard to failure to warn, BSC argues that "the plaintiffs offered no evidence that a different warning would have caused their physicians not to implant the Obtryx." (BSC's Mem. of Law in Supp. of Its Mot. for New Trials ("BSC's Mem. re: New Trials") [Docket 580], at 10–11). In my discussion of Dr. Bhanot related to BSC's Renewed Motion, I acknowledged the doctor's inconsistent testimony regarding the MSDS, but deferred to the jury's assessment of the witness. I too find his testimony adequately establishes proximate causation.

Upon direct examination, Dr. Bhanot testified that he would not have used the Obtryx for the specific plaintiffs in this case had he known about the MSDS. (Bhanot Dep. Tr. [Docket 570-5], at 238:9–240:10). Upon cross-examination, Dr. Bhanot agreed that he would continue to use the Obtryx "when appropriate," and that he has not and would not rely on statements from the polypropylene manufacturer in deciding whether to use the Obtryx or in discussing a device's risks with his patients. (Bhanot Dep. Tr. [Docket 570-15], at 380:4–16, 394:16–395:21). First, whether Dr. Bhanot will or will not continue to use the Obtryx for certain patients in the future is separate and distinct from whether, in hindsight, he would still choose to use the Obtryx for Ms. Wilson and Ms. Campbell. Dr. Bhanot clearly stated that he would not have used the Obtryx for these two plaintiffs had he been provided with certain information. Furthermore, although Dr. Bhanot indicated that he would not have relied on information from Phillips Sumika, the polypropylene

manufacturer, in making his decision to recommend the Obtryx to the plaintiffs, (*id.* at 395:23–396:3), he did rely on the information in the DFU, which was provided by BSC. (Bhanot Dep. Tr. [Docket 570-5], at 199:21–200:4). Therefore, I can infer that, had BSC warned of the risks associated with permanent implantation in the DFU, Dr. Bhanot would have relied on those warnings and chosen a different product. Accordingly, Dr. Bhanot's testimony supports a finding of proximate causation.

Thus, considering the case in its entirety, I do not find the jury's verdict to be erroneous. Absent such a finding, BSC's Motion on this issue is **DENIED**.

4. Trial Errors

Lastly, BSC points to three sets of alleged errors that occurred at trial, resulting in a miscarriage of justice.

a. Evidentiary Rulings

The Supreme Court has stated that "alleged substantial errors in admission or rejection of evidence" may warrant a new trial. *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940). To succeed on this theory, BSC must demonstrate that the alleged evidentiary errors were *substantial*. *See id.*; *see also Creekmore v. Maryview Hosp.*, 662 F.3d 686, 693 (4th Cir. 2011) (holding that the court will not set aside a judgment on this basis "unless justice so requires or a party's substantial rights are affected"). As explained below, none of BSC's arguments—taken individually or together—convey the substantial error required to secure a new trial.

i. FDA Evidence

BSC argues that the exclusion of evidence related to the FDA's 510(k) clearance process was "incredibly prejudicial" and "resulted in verdicts based on a false premise." (BSC's Mem. re: New Trials [Docket 580], at 12, 14). I have addressed this argument multiple times throughout the

course of these MDLs, each time reaching the same conclusion: the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. *See, e.g.*, *Cisson v. C. R. Bard, Inc.*, 86 F. Supp. 3d 510, 517 (S.D. W. Va. 2015), *available at* 2015 WL 566959; *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp. (Sanchez I)*, No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

The Fourth Circuit recently affirmed this court's determination that the probative value of evidence related to 510(k) clearance is substantially outweighed by its possible prejudicial impact and was properly excluded under Rule 403. *In re C. R. Bard*, 810 F.3d at 922 (crediting the district court's concern that "subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it").

Federal Rule of Evidence 401 provides that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. In light of the Supreme Court's precedent on the meaning and purpose of 510(k), I see little relevance in the fact that the Obtryx was cleared pursuant to this process. In *Medtronic, Inc. v. Lohr*, the Supreme Court held that compliance with 510(k) focuses on "equivalence, not safety" and that products entering the market through the 510(k) process have "never been formally reviewed [for] safety or efficacy." 518 U.S. 470, 493 (1996). If 510(k) does not go to a product's safety and efficacy—the "very subjects" of the plaintiffs' products liability claims, *Riegel v. Medtronic, Inc.*, 552 U.S 312, 322 (2008)—then evidence of BSC's compliance with 510(k) has no relevance to the state law claims in this case and was properly excluded by the court. *See* Fed. R. Evid. 402

("Irrelevant evidence is not admissible."); *see also In re C. R. Bard, Inc.*, 810 F.3d at 920 (4th Cir. 2016) (noting that "the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value" in products liability cases).

Even if evidence on FDA rules and regulations had some relevance to this case, the balancing test set forth in Rule 403 of the Federal Rules of Evidence nevertheless forecloses BSC's argument in favor of a new trial. Rule 403 provides that a court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. In previous cases, I explained how FDA evidence succumbs to this rule:

> Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. [Furthermore,] "the jury may attach undue significance" to an FDA determination, and [] "alleged shortcomings in FDA procedures are not probative to a state law products liability claim."

Lewis, 991 F. Supp. 2d at 754–55; *see also Sanchez v. Boston Scientific Corp. (Sanchez II)*, No. 2:12-cv-05762, 2014 WL 4851989, at *35 (S.D. W. Va. Sept. 29, 2014) ("[T]estimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about [the state law claims] than enlightenment."). Additionally, the admission of FDA evidence might have provoked the parties to engage in a time-consuming mini-trial on whether BSC in fact complied with its regulations. In short, because going down the road of federal regulatory schemes—which do not concern any of the state law claims at issue—would risk confusing and misleading the jury, this court was correct in excluding FDA evidence.

More specifically, BSC claims that the court's exclusion of FDA evidence unfairly prevented BSC from demonstrating that the FDA knew about and considered the MSDS in its 510(k) clearance of the Obtryx. This argument "exaggerates the importance of the § 510(k)

process." *Lohr*, 518 U.S. at 492. No matter the materials reviewed by the FDA in the 510(k) process, the result is the same—510(k) clearance does not speak to the safety and effectiveness of a product or the raw materials forming it. *See id.* at 493. The FDA's consideration of the MSDS therefore has little probative value and would have served only to confuse the jury.

ii. Dr. Pence/Industry Standards

BSC takes issue with the court's findings in the Memorandum Opinion and Order related to BSC's *Daubert* challenges of Dr. Peggy Pence's opinion about the inadequacy of pre-market testing of the Obtryx. BSC asserts that the court was mistaken in concluding that Dr. Pence bolstered her opinions with certain sources because those sources dealt with the use of mesh for pelvic organ prolapse rather than the Obtryx, an SUI product. (BSC's Mem. re: New Trials [Docket 580], at 14). My *Daubert* ruling speaks for itself on the issue of whether or not Dr. Pence's opinions were properly supported, and I see no need to revisit it. (Memorandum Opinion and Order (*Daubert* Motions) [Docket 444], at 43-44).

BSC also takes issue with my *Daubert* rulings excluding the opinions of its expert, Dr. Christine Brauer, while permitting Dr. Pence to testify about the inadequacy of pre-market testing. I excluded Dr. Brauer's opinions because they related to the 510(k) process, a decision I have now made several times before (as noted above), even as to Dr. Brauer in particular. (Memorandum Opinion and Order (*Daubert* Motions) [Docket 444], at 107-08). Nevertheless, BSC again challenges my ruling related to Dr. Brauer, this time asserting that

> Dr. Pence's opinion that a reasonably prudent medical device manufacturer would have performed pre-market clinical testing is belied by the 510(k) process itself, which allows manufacturers to market a device without such testing if FDA finds the device substantially equivalent to [i.e., as safe and effective as] a previously approved device. While it may be the plaintiffs' position that a reasonable manufacturer would have taken steps in addition to complying with the federal regulatory scheme, concealing the existence of that scheme from the jury was unreasonable. Allowing Dr. Pence to offer 'industry standards' testimony based on

> random studies and her experience while excluding Dr. Brauer's opinions based on the federal regulations that actually apply to medical device manufacturers in the United States unfairly prejudiced Boston Scientific.

(BSC's Mem. re: New Trials [Docket 580], at 15).

BSC's arguments are simply a rehash of arguments I have considered many times before, and I find them wholly unconvincing. The Federal Rules of Civil Procedure permit a court to reconsider and revise interlocutory orders:

> [A]ny order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Fed. R. Civ. P. 54(b); *see also Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1469 (4th Cir. 1991) ("An interlocutory order is subject to reconsideration at any time prior to the entry of a final judgment."). The *Daubert* orders here fall within the scope of this rule, and BSC could have moved for reconsideration, but did not. Like other interlocutory rulings, *Daubert* rulings are subject to reconsideration under the appropriate circumstances, including "a controlling or significant change in the law or facts since the submission of the issue to the Court." *Above the Belt, Inc. v. Mel Bohnannan Roofing, Inc.*, 99 F.R.D. 99, 101 (E.D. Va. 1983). BSC has offered no such change in the law or facts.

In its reply, BSC contorts the issue further by asserting that

> the trial itself reveals the unfair prejudice caused by the Court's rulings … the jury was entitled to hear about FDA requirements, which were inseparable from industry standards, and FDA clearance, both because the jury was tasked with determining what a reasonably prudent manufacturer would have accomplished with respect to safety and more particularly because plaintiffs were permitted to mislead the jury at trial.

(BSC's Reply Mem. Of Law in Supp. of Its Mot. for New Trials [Docket 606], at 9-10).

BSC's argument is misleading because it suggests that Judge Berger did not allow Dr.

Brauer to testify at trial. To the contrary, there is nothing in the record to suggest Dr. Brauer was called to give any other opinion or fact testimony, or even called as a witness at all; BSC simply offered a proffer of her 510(k) testimony.

In addition to the sound reasons for excluding Dr. Brauer before trial coupled with BSC's failure to raise the issue again at trial, when asked about industry standards on cross-examination, Dr. Pence admitted that the vast majority of mid-urethral slings on the market today were never subject to clinical trials. (*Id.* at 333:1–5). Therefore, additional expert testimony was not necessary to introduce this evidence to the jury in any event, and BSC was not unfairly prejudiced in the court's exclusion of Dr. Brauer.

b. Closing Argument

During closing argument, counsel is not permitted to ask jurors to place themselves in the position of a party. *See Ins. Co. of N. Am., Inc. v. U.S. Gypsum Co.*, 870 F.2d 148, 154 (4th Cir. 1989). This kind of "deliberate appeal to the jury to substitute sympathy for judgment" is known as a "golden rule" argument. *Leathers v. Gen. Motors Corp.*, 546 F.2d 1083, 1088 (4th Cir. 1976) (Widener, J., concurring and dissenting) (quoting *Klotz v. Sears, Roebuck, Co.*, 267 F.2d 53, 55 (2d Cir. 1959)). "Such a 'golden rule' argument does not constitute reversible error if no prejudice arise[s] from counsel's comment." *Gypsum*, 870 F.2d at 154.

BSC challenges two sets of statements offered by plaintiffs' counsel during closing argument. First:

> In addition to this constant pain, all of these women could have intercourse, intimate relations with the people they love most in life prior to this surgery. None of them are having it now.
>
> And I've thought about how to describe what that must be like, and I can't. I'm not a woman. I don't know. And it's difficult. And I got married late in life. I'm 45. I got married five years ago. I lost my wedding ring in this trial and my wife is going to kill me. But, I got married late.

> Jeanie is my age. And I've got my whole life ahead of me with the woman I love most. And the thought of me not being intimate with her for five years, ten years, 20 years, not just the act. I mean we're human beings. That's how we express how we love and share that emotion with the one we love most in life. Right? The one that's most intimate with us.
>
> And it's not really so much the act. The act is important because it is how we express love. But it's knowing that you can't provide for that person the way that all of your friends do, the way that your neighbors do, the way that everybody else in this courtroom can.
>
> And think about how that weighs on you every morning knowing the guy or gal that I love most, I can't provide. I can't give them what everyone else can in a loving relationship.

(Trial Tr. (Nov. 19, 2014) [Docket 542], at 2278:19–2279:15). At this point, BSC objected based on the golden rule, and Judge Berger overruled the objection. (*Id.* at 16–23 ("Mr. Adams, I think it is close, but I'm going to overrule the objection, preserving your objection and exception.")). Plaintiffs' counsel continued:

> And you heard it from Jeanie Blankenship, the emotional toil every day you wake up. Right? Another day that I can't give my boyfriend, my spouse what everybody else can. Going to bed every night, what's next with this thing?
>
> And all of us have had that week, you know, where you have – crappy weeks. Right? You're sick, whatever it is. And every day you're in a bad mood. And at the end of the week, you're taking it out on your friends, your spouse, your co-workers because you've just been grumpy. Think about that every day, every day.
>
> . . . .
>
> So, when I told you at the beginning of the case this was a big case with big damages, it is.
>
> Because I'll take a broken leg, a broken back, a surgery any day over what these women are going through every day. These women are way stronger than I could ever comprehend.

(*Id.* at 2279:24–2280:20). BSC did not object to the remainder of counsel's argument.[15]

[15] In *Ray v. Allergan*, the United States District Court for the Eastern District of Virginia discussed the conflict in the Fourth Circuit regarding whether failing to object to a closing argument waives the right to attack the verdict on a

Upon review, I agree with Judge Berger's ruling at trial and **FIND** that plaintiffs' counsel's argument was not so egregious as to require a new trial. Mr. Love specifically framed this portion of his argument with references to himself, not the jury. (*See* Trial Tr. (Nov. 19, 2014) [Docket 542], at 2278:19–24, 2280:16–20 ("And *I've* thought about how to describe what that must be like, and *I* can't. . . . Because *I'll* take a broken leg, a broken back, a surgery any day over what these women are going through every day. These women are way stronger than *I* could ever comprehend." (emphases added))). I find that Mr. Love used the word "you" in an impersonal sense, which is not error. *See Leathers*, 546 F.2d at 1087. Furthermore, Judge Berger's additional instructions to the jury following closing argument clearly stated that the verdicts "must be based solely on the evidence and on the law." (Trial Tr. (Nov. 19, 2014) [Docket 542], at 2332:4–5). I likewise reject BSC's remaining objections. Therefore, because sufficient prejudice to BSC is lacking, the motion on this issue is **DENIED**.

c. Punitive Damages Instruction

"Instructions are adequate if 'construed as a whole, and in light of the whole record, they adequately inform the jury of the controlling legal principles without misleading or confusing the jury to the prejudice of the objecting party.'" *S. Atl. Ltd. P'ship of Tenn., L.P. v. Riese*, 284 F.3d 518, 530 (4th Cir. 2002) (quoting *Spell v. McDaniel*, 824 F.2d 1380, 1395 (4th Cir. 1987)). "Even if instructions are flawed, there can be no reversal unless the error seriously prejudiced the challenging party's case." *Id.*

BSC objects to the following statement given by Judge Berger: "You are instructed that if

motion for new trial. 863 F. Supp. 2d 552, 565–67 (attempting to harmonize the Fourth Circuit's decisions in *Dennis v. General Electric Corp.*, 762 F.2d 365 (4th Cir. 1985), and *Werner v. Upjohn Company, Inc.*, 628 F.2d 848 (4th Cir. 1980)). The court ultimately concluded that a golden rule violation "is excused from the contemporaneous objection requirement." *Id.* at 567. In light of *Ray*, I, out of an abundance of caution, will review both sets of challenged statements, despite BSC's failure to object to the second at trial.

you find by a preponderance of the evidence that the acts of the defendant were willful, wanton, malicious, oppressive, fraudulent, or with reckless disregard for the plaintiff, then you may award punitive damages against the defendant." (Trial Tr. (Nov. 19, 2014) [Docket 542], at 4–10). BSC contends that this instruction led the jury to believe that it could *award* an amount of punitive damages during the first phase of trial rather than just find BSC *liable* for punitive damages. I disagree and **FIND** that the instruction given by Judge Berger, taken in its entirety and considered together with the verdict form, did not mislead the jury to the prejudice of BSC.

To elaborate, I provide Judge Berger's instructions related to punitive damages in full:

> If you find that a plaintiff is entitled to an award of compensatory damages, then you may also consider whether the plaintiff is entitled to any punitive damages. Punitive damages are damages that are awarded to punish a defendant who has damaged the plaintiff by acting willfully, wantonly, maliciously, or oppressively, or through gross fraud, or by reckless conduct affecting the rights of others. They're intended to deter the defendant and others from engaging in a similar course of conduct in the future.
>
> Punitive damages are not compensation for injury. An award of punitive damages means that you, the jury, believe that the defendant should be punished for its conduct as proven by the evidence in this case.
>
> A plaintiff is not entitled to punitive damages as a matter of right. In other words, even if you find that a defendant's conduct rises to the level of gross fraud, malice or oppression, wanton, willful, or reckless conduct, the decision to impose or to withhold punitive damages lies within your sound discretion.
>
> You are instructed that if you find by a preponderance of the evidence that the acts of the defendant were willful, wanton, malicious, oppressive, fraudulent, or with reckless disregard for the plaintiff, then you may award punitive damages against the defendant. *If you so find, the Court will give you further instructions on the issue of punitive damages.*

(*Id.* at 2254:10–2255:10 (emphasis added)). Judge Berger clearly explained that it was within the jury's discretion to decide whether punitive damages were justified in this case. Furthermore, at the end of her instruction, Judge Berger indicated that if the jury found BSC engaged in the requisite conduct, they would be provided with further instructions on the issue of punitive

damages. The verdict forms also clearly delineated the issue of punitive damages by first asking for the amount of compensatory damages proven, and then asking only whether the plaintiffs had shown BSC acted with the requisite conduct necessary to award punitive damages. (*See* Verdict Form for Jeanie Blankenship [Docket 522]; Verdict Form for Carol Campbell [Docket 530]; Verdict Form for Chris Wilson [Docket 534]). The jury was never asked to award a specific amount of punitive damages during the first phase of trial. Accordingly, the court's instruction on punitive damages was not so erroneous as to warrant new trials.

IV. Conclusion

BSC has asked this court to discard the jury's unanimous decision and direct a verdict in its favor pursuant to Rule 50(b), which allows for a directed verdict only if no reasonable jury could find in the plaintiffs' favor. BSC has also asked for a new trial pursuant to Rule 59, which allows for a do-over only if a grievous error occurred that rendered the trial unfair. Both courses of action require the court to desert the jury's verdict, and consequently, neither should be taken lightly. Indeed, the remedies of a directed verdict or a new trial should be applied only in exceptional circumstances. BSC has failed to show that such circumstances exist here. Thus, applying the hesitancy and caution that a district court must employ in these circumstances, I **DENY** BSC's Renewed Motion [Docket 581] and Motion for New Trials [Docket 579] as to plaintiffs Wilson, Campbell and Blankenship and **DENY as moot** BSC's Renewed Motion [Docket 581] and Motion for New Trials [Docket 579] as to Ms. Tyree.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 3, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE